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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,270	01/22/2002	Edward P. Perez	7404-318	6329

7590

05/28/2003

Woodard, Emhardt, Naughton, Moriarty and McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER

DAVIS, DANIEL J

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 05/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

8c

Office Action Summary

Application No.

10/054,270

Applicant(s)

PEREZ ET AL.

Examiner

D Jacob Davis

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on IDS 11/21/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 4,6-9,20,24-31,34,37,38 and 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,10-12,15-19,21-23,32,33,35,36 and 39-42 is/are rejected.
- 7) ☒ Claim(s) 5,13 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3731

DETAILED ACTION***Election/Restrictions***

This application contains claims directed to the following patentably distinct species of the claimed invention:

<u>SPECIES</u>	<u>REPRESENTATIVE FIGURE</u>
1	1A
2	3A
3	4B
4	4C
5	4D
6	4F
8	4H
9	5A
10	6A
11	7
12	8A
13	9A

During a telephone conversation with Charles Meyer on April 28, 2003 a provisional election was made without traverse to prosecute the invention of Species 1, claims 1-3, 5, 10-19, 21-23, 32, 33, 35, 36 and 39-42. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4, 6-9, 20, 24-31, 34, 37, 38, and 43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

Art Unit: 3731

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Art Unit: 3731

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 10-12, 15, 22, 23, 32, 33, 35, 36, 39, 40 and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by Douglas et al. (US 6,048,352). Douglas discloses in Figs. 16-17 a device for sampling body fluid comprising a main body 94 defining a capillary channel and a lancet 96. The lancet is selectively advanceable and retractable (Col. 8, lines 7--et seq.). Because of the small annular space between the

Art Unit: 3731

lancet and the main body, body fluid is inherently drawn into the annular space through capillary action. The device further comprises a testing element/test strip 19 that is in communication with the annular space. There is a dividing wall between passages 92 and 94 that enables communication between the two passages.

The device comprises a spring biasing means to retract the lancet (Col. 8, lines 20-22). The device further comprises biasing means to selectively advance the lancet (Col. 8, lines 14-20). The body is generally cylindrically shaped.

With respect to claim 33-36, once the fluid is drawn into the annular space, it will inherently be retained in the space due to surface tension forces. (See U.S. Pat. 5,322,609 to Graham; Col. 3, lines 47-51) The fluid tested and the fluid retained in the fluid retained in the annular space is all one fluid. The testing means communicates with the channel. The testing means is used to test the blood glucose level (Col. 1, lines 35-39).

Claim 16 is rejected under 35 U.S.C. 102(e) as anticipated by Douglas or, in the alternative, under 35 U.S.C. 103(c) as obvious over Douglas in view of Plum (US 5,298,224). Douglas discloses a lancet device used to obtain a blood sample but is silent regarding the material of the capillary tube. Nevertheless, inherently the capillary tube is made of biocompatible plastic because of its biocompatible nature, low cost, and inert properties. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the capillary tube out of plastic as

Art Unit: 3731

taught by Plum (Col. 1, line 67—col. 2, line 2) because of its biocompatible nature, low cost, and inert properties.

Claims 21 and 41 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(c) as obvious over Douglas. The lancet of the Douglas device inherently advances between approximately 0.05 mm and 3 mm and retracts between 0 and 2 mm from the site. In the alternative, it would have been obvious to one of ordinary skill in the art at the time the invention was made to advance the lancet between 0.05 mm and 3 mm to maximize lancet control and optimize the tissue entry force. Also, it would have been obvious to one of ordinary skill in the art at the time the invention was made to retract the lancet between 0 and 2 mm from the site to remove the lancet from the target site to prevent accidental injury and to allow for blood flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(c) as being unpatentable over Douglas in view of admitted prior art. Douglas discloses a test strip but is silent regarding the manner of testing. Nevertheless, applicants admit in the specification that optically reactive test strips are known in the art as a means to test blood.

Claims 18 and 19 are rejected under 35 U.S.C. 103(c) as being unpatentable over Douglas in view of Graham (US 5,322,609). Douglas is silent regarding the transparency of the capillary tube. Nevertheless, Graham discloses a transparent capillary tube to allow a user to visualize the amount of blood in the capillary tube as it is being filled. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make Douglas's capillary tube transparent to visualize the amount of blood in the capillary tube as it is being filled. The entire capillary tube, including the passage defining the lancet, would be of the same transparent material to reduce manufacturing costs and processes.

Allowable Subject Matter

Claims 5, 13, and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3731


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D Jacob Davis whose telephone number is (703) 305-1232. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

DJD
May 8, 2003


DAVID O. REIP
PRIMARY EXAMINER